UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC., Plaintiff, v. CYPRESS PHARMACEUTICAL, INC., Defendant.	Civil Action No.: 12-cv-6851-AJN ECF Case **ANSWER AND COUNTERCLAIMS OF DEFENDANT CYPRESS PHARMACEUTICAL, INC.**

Defendant, Cypress Pharmaceutical, Inc. ("Cypress"), by and through its undersigned counsel, hereby answers the Complaint of Braintree Laboratories, Inc. ("Braintree") as follows:

PARTIES

1. Braintree is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, MA 02185-0929.

Answer: Cypress is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 of the Complaint and therefore denies them.

2. Upon information and belief, Cypress Pharmaceutical, Inc. ("Cypress") is a corporation organized and existing under the laws of the State of Mississippi, having a principal place of business at 135 Industrial Blvd., Madison, MS 39110.

Answer: Cypress admits the allegations of Paragraph 2 of the Complaint.

3. Upon information and belief, following any FDA approval of ANDA No 204135, Cypress will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No 204135 throughout the United States, and/or import such generic products into the United States.

Answer: Cypress admits only that, upon final FDA approval, it may make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No 204135

throughout the United States, and/or import such generic products into the United States. Cypress denies the remaining allegations of Paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U. S .C. §§ 1391 and 1400(b).

Answer: Cypress admits that this action is styled as one for the alleged violation of the patent laws of the United States, Title 35, United States Code, more particularly, 35 U.S.C. § 271, *et seq*, but denies that the allegations have any merit. Cypress further admits that Braintree purports to base subject matter jurisdiction on 28 U.S.C. §§ 1331 and 1338(a). Cypress admits that venue is proper in this Court under 28 U. S .C. §§ 1391 and 1400(b), but avers that this judicial district is not the most appropriate venue for this lawsuit.

5. Upon information and belief, this Court has personal jurisdiction over Cypress, because, *inter cilia*, Cypress has purposely availed itself of the rights and benefits of the laws of New York by engaging in persistent, systematic and continuous contacts with New York, such that it should reasonably anticipate being subject to suit here. In particular, Cypress selected New York County on its "Application for authority" to do business in New York as the "county...in which its office is to be located," and designated the New York Secretary of State as its "agent upon whom process against it may be served." ***See* Exhibit A** (New York State corporate status information for Cypress); New York Business Corporation Law §§ 1304(a)(5); (a)(6). New York County (Manhattan) is within the Southern District of New York.

Answer: The allegations of Paragraph 5 of the Complaint state legal conclusions to which no response is required. Cypress will not contest that this Court has personal jurisdiction over it for the purposes of this action. Except as expressly admitted, Cypress denies the allegations of Paragraph 5 of the Complaint.

6. Upon information and belief, Cypress regularly and continuously transacts business within the State of New York, including availing itself of the privilege of conducting business within New York by selling pharmaceutical products there. Upon information and belief, Cypress derives substantial revenue from its New York drug sales. For instance, Cypress has numerous reimbursed products listed in the New York State Department of Health Medicaid system. *Available at* **https://www.emedny.org/info/fullform.pdf.**

Answer: The allegations of Paragraph 6 of the Complaint state legal conclusions to which no response is required. Cypress will not contest that this Court has personal jurisdiction over it for the purposes of this action. Except as expressly admitted, Cypress denies the allegations of Paragraph 6 of the Complaint.

7. Upon information and belief, Cypress will manufacture, market, and/or sell within the United States the generic version of Braintree's SUPREP® drug product described in Cypress' ANDA No. 204135 if FDA approval is granted. If ANDA No. 204135 is approved, the generic version of Braintree's SUPREP® charged with infringing the '149 Patent, would, upon information and belief, be marketed and distributed in New York, prescribed by physicians practicing in New York, dispensed by pharmacies located within New York, be listed as a reimbursed product in the New York State Department of Health Medicaid system, and/or used by persons in New York, all of which would have a substantial effect on New York.

Answer: Cypress admits only that upon final FDA approval it may manufacture, market, and/or sell within the United States the generic version of Braintree's SUPREP® drug product defined by Cypress' ANDA No. 204135. Cypress is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 7 of the Complaint and therefore denies them.

8. In addition, upon information and belief, Cypress has previously availed itself of this forum for the purpose of litigating patent disputes. In *Glaxo Group Limited v. Cypress Pharmaceutical, Inc.*, Case No. 1:07-cv-06012-RJH (S.D.N.Y), Cypress admitted that it was subject to personal jurisdiction in this District and filed counterclaims seeking declaratory judgments of invalidity and non-infringement.

Answer: Cypress admits that it litigated the cited case in this judicial district, but denies the remaining allegations of Paragraph 8 of the Complaint.

BACKGROUND

9. Braintree holds approved New Drug Application ("NDA") No. 22372 for SUPREP® Bowel Prep Kit ("SUPREP"). SUPREP is a sodium sulfate, potassium sulfate and magnesium sulfate osmotic laxative and was approved by the FDA on August 5, 2010. SUPREP is indicated for bowel cleansing prior to an adult patient having a colonoscopy procedure.

Answer: Cypress admits that SUPREP® is a sodium sulfate, potassium sulfate and magnesium sulfate osmotic laxative. With respect to the remaining allegations of Paragraph 9 of the Complaint, Cypress denies the allegations to the extent they conflict with the information set forth in the FDA's records relating to NDA No. 22372 for the SUPREP® Bowel Prep Kit. Except as expressly admitted above, Cypress denies the allegations of Paragraph 9 of the Complaint.

10. Pursuant to 21 U.S.C. § 355 (b)(i) and attendant FDA regulations, the '149 patent has been listed in connection with SUPREP in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is referred to as the "Orange Book." SUPREP, or its use or formulation, is covered by one or more claims of the '149 patent.

Answer: Cypress admits that the '149 patent is listed in the Orange Book in connection with SUPREP®. The remaining allegations of Paragraph 10 are legal conclusions to which no response is required.

THE '149 PATENT

11. Braintree is the lawful owner by assignment of the '149 patent, entitled "Salt Solution for Colon Cleansing," duly and legally issued by the U.S. Patent and Trademark Office on September 20, 2005. The '149 patent was the subject of an *ex parte* reexamination procedure that was requested on October 15, 2008. A reexamination certificate was issued by the U.S. Patent and Trademark Office on June 30, 2009. As a result of the reexamination, it was determined that claims 1, 6, 8-9, 13-14, 17 and 21 were cancelled, claims 2-4, 7, 10, 15 and 18 were determined to be patentable as amended, and claims 5, 11-12, 16, 19-20 and 22-23, each dependent on an amended claim, were also determined to be patentable. A true and correct copy of the '149 patent and its reexamination certificate are attached hereto as **Exhibit B.** The claims of the '149 patent are valid and enforceable.

Answer: Cypress admits that, on the face of the documents, it is indicated the United States Patent and Trademark Office ("PTO") issued the '149 patent on September 20, 2005 and that the PTO issued a reexamination certificate on that patent on June 30, 2009, but denies that either document was duly and legally issued. Cypress further admits that what purports to be a copy of the '149 patent and its reexamination certificate are attached to the

Complaint as Exhibit B. Cypress is without knowledge or information sufficient to form a belief as to the truth of the remainder of the factual allegations of Paragraph 11 of the Complaint and therefore denies those allegations. To the extent any of the remaining allegations of Paragraph 11 of the Complaint are legal conclusions, no response is necessary.

12. The '149 patent, *inter alia*, claims a composition and a method for use of the composition to cleanse the colon.

Answer: The allegations of Paragraph 12 of the Complaint state legal conclusions to which no response is required. Cypress refers to the claims of the '149 patent for the contents thereof and otherwise denies the allegations of Paragraph 12 of the Complaint.

13. The '149 patent expires on March 7, 2023, which includes the associated patent term adjustment.

Answer: The allegations of Paragraph 13 of the Complaint state legal conclusions to which no response is required. To the extent any allegations of Paragraph 13 of the Complaint are factual, Cypress is without knowledge or information sufficient to form a belief as to their truth and therefore denies them.

14. Braintree, as the owner of the entire right, title and interest in the '149 patent, possesses the right to sue for infringement of the '149 patent.

Answer: The allegations of Paragraph 14 of the Complaint state legal conclusions to which no response is required. Cypress is without knowledge or information sufficient to form a belief as to the truth of the factual allegations of Paragraph 14 of the Complaint and therefore denies them.

INFRINGEMENT BY CYPRESS

15. By letter dated July 31, 2012 ("Cypress Notice Letter"), Cypress notified Braintree that Cypress had submitted ANDA No. 204135 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, or sale and/or importation of the sodium sulfate, potassium sulfate

and magnesium sulfate oral lavage solution currently listed in the Orange Book for SUPREP, prior to the expiration of the '149 patent.

Answer: Cypress admits that it notified Braintree by letter dated July 31, 2012 that it had submitted ANDA No. 204135 ("the Cypress ANDA") to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), which ANDA named SUPREP® as the reference listed drug ("Cypress Notice Letter"). Cypress avers that the Cypress Notice Letter stated that, although Cypress sought approval for its generic product prior to the expiration of the '149 patent, the commercial manufacture, use, sale, offer for sale and/or importation of the generic product defined in the Cypress ANDA would not infringe any valid claim of the '149 patent, and set forth a detailed explanation of each of the several bases for its belief. Cypress otherwise denies the allegations of Paragraph 15 of the Complaint.

16. By filing ANDA No. 204135, and upon information and belief, Cypress has represented to the FDA that the components of its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, respectively 17.5g/3.13g/1.6g per bottle, have the same active ingredients, the same route of administration, dosage form, and the same strengths as the corresponding components of SUPREP. Upon information and belief, Cypress has represented that its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution is bioequivalent to SUPREP.

Answer: Cypress admits that it filed ANDA No. 204135 which ANDA named SUPREP® as the reference listed drug and that, upon information and belief, the ANDA establishes bioequivalence to SUPREP®. To the extent the allegations of Paragraph 16 of the Complaint are legal conclusions, no response is necessary. Except as expressly admitted above, Cypress denies the allegations of Paragraph 16 of the Complaint.

17. Cypress has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No 204135 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of generic sodium sulfate, potassium sulfate, magnesium sulfate oral lavage solution before the expiration of the '149 patent.

Answer: Denied. To the extent the allegations of Paragraph 17 of the Complaint are legal conclusions, no response is necessary.

18. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Cypress's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No 204135, relating to Cypress's proposed generic oral lavage solution, shall not be earlier than the expiration of the exclusivity afforded the '149 patent.

Answer: Denied. To the extent the allegations of Paragraph 18 of the Complaint are legal conclusions, no response is necessary.

19. This Complaint is being filed before the expiration of the forty-five day period from the day after Braintree received the Cypress Notice Letter.

Answer: Admitted.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY CYPRESS)

20. Each of the preceding paragraphs 1 through 19 is incorporated as if fully set forth.

Answer: Cypress realleges and incorporates by reference each of its responses to paragraphs 1 through 19 of the Complaint.

21. Cypress's submission of ANDA No. 204135 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of sodium sulfate, potassium sulfate and magnesium sulfate oral solution prior to the expiration of the '149 patent constitutes infringement of one or more of the claims of the '149 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Denied. To the extent the allegations of Paragraph 21 are legal conclusions, no response is necessary.

22. Upon information and belief, Cypress had actual and constructive knowledge of the '149 patent prior to filing ANDA No 204135 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '149 patent.

Answer: Cypress admits that it had knowledge of the '149 patent when it filed ANDA No. 204135, but denies the remaining factual allegations of Paragraph 22 of the Complaint. To the extent the allegations of Paragraph 22 are legal conclusions, no response is necessary.

23. Upon information and belief, use of generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution in accordance with and as directed by the proposed labeling in ANDA No 204135 for that product would infringe one or more claims of the ‘149 patent.

Answer: Denied. To the extent the allegations of Paragraph 23 are legal conclusions, no response is necessary.

24. Upon information and belief, Cypress knows that its generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, and the proposed labeling for that product, are especially made or adapted for use in infringing the '149 patent, and that the generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Cypress plans and intends to, and will induce and/or contribute to the infringement of the '149 patent immediately and imminently upon approval of ANDA No. 204135.

Answer: Denied. To the extent the allegations of Paragraph 24 are legal conclusions, no response is necessary.

25. Upon FDA approval of Cypress's ANDA No. 204135, Cypress will infringe the ‘149 patent by making, using, offering to sell, and selling generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution in the United States and/or importing such solution into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

Answer: Denied. To the extent the allegations of Paragraph 25 are legal conclusions, no response is necessary.

26. If infringement of the ‘149 patent by Cypress is not enjoined, Braintree will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Answer: Denied. To the extent the allegations of Paragraph 26 are legal conclusions, no response is necessary.

REQUEST FOR RELIEF

Cypress denies that Braintree is entitled to any relief whatsoever against Cypress in this action and denies all of the requests and/or allegations contained in Paragraphs 1 through 4 of Braintree’s Request for Relief.

DEFENSES

Without any admission as to burden of proof and expressly reserving its right to assert additional defenses or counterclaims that discovery may reveal, Cypress states the following defenses:

1. The '149 patent is invalid for failing to meet the requirements of patentability, including without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or for improper double patenting.

2. Cypress does not infringe, contribute to the infringement of, or induce others to infringe any valid claim of the '149 patent either literally, under the doctrine of equivalents, directly, indirectly, willfully, or otherwise.

3. The doctrines of prosecution history estoppel (by argument or by amendment) and disclaimer preclude any finding of infringement of certain claims of the '149 patent.

4. The Complaint fails to state a claim upon which relief can be granted.

5. Braintree cannot prove that this is an exceptional case under 35 U.S.C. § 285.

6. Braintree's claims for damages and costs are statutorily limited, at the least, by 35 U.S.C. § 288.

7. Cypress denies each and every allegation of the Complaint not specifically admitted, controverted or denied herein.

COUNTERCLAIMS

Defendant and Counterclaim-Plaintiff Cypress Pharmaceutical, Inc. ("Cypress") brings the following Counterclaims against Plaintiff/Counterclaim-Defendant, Braintree Laboratories, Inc. ("Braintree"), and states as follows:

PARTIES

1. Cypress is a corporation organized and existing under the laws of the State of Mississippi with a principal place of business at 135 Industrial Boulevard, Madison MS 39110.

2. Braintree alleges that it is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, MA 02185-0929.

3. Braintree alleges that it is the owner by assignment of United States Patent No. 6,946,149, as reexamined ("the '149 patent").

4. In its Complaint, Braintree has alleged that Cypress has committed an act of infringement under 35 U.S.C. § 271(e)(2) by filing an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of the generic product defined in ANDA No. 204135 ("the Cypress Generic Product") before the expiration of the '149 patent. Braintree further alleged in its Complaint that the Cypress Generic Product, if manufactured, used, offered for sale or sold in the United States, and/or imported into the United States, would infringe one or more claims of the '149 patent.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 2201, 2202, 1331, and 1338.

6. This Court has personal jurisdiction over Braintree because, *inter alia*, Braintree has subjected itself to the jurisdiction of this Court by filing the present action.

7. In view of Braintree's filing of this action, venue for adjudication of these Counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

COUNT 1
DECLARATION OF NO INFRINGEMENT
OF UNITED STATES PATENT NO. 6,946,149

8. Cypress repeats and realleges the allegations of Paragraphs 1 through 7 of the Counterclaims as if fully set forth herein.

9. There is a substantial and continuing controversy between Cypress and Braintree resulting from Braintree's assertion of infringement of the '149 patent.

10. The filing of an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of the Cypress Generic Product before the expiration of the '149 patent was not an act of infringement of any valid and/or enforceable claim of the '149 patent, either literally or under the doctrine of equivalents, directly, indirectly, willfully, or otherwise.

11. Cypress is entitled to a declaration that the filing of an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of the Cypress Generic Product before the expiration of the '149 patent was not an act of infringement of any valid and/or enforceable claim of the '149 patent, either literally or under the doctrine of equivalents, directly, indirectly, willfully, or otherwise.

12. This is an exceptional case under 35 U.S.C. § 285 entitling Cypress to an award of attorneys' fees in connection with this action.

COUNT II
DECLARATION OF INVALIDITY
OF UNITED STATES PATENT NO. 6,946,149

13. Cypress repeats and realleges the allegations of Paragraphs 1 through 12 of the Counterclaims as if fully set forth herein.

14. There is a substantial and continuing controversy between Cypress and Braintree resulting from Braintree's assertion of infringement of the '149 patent.

15. One or more of the claims of the '149 patent are invalid for failure to satisfy one or more requirements under the patent laws of the United States, including without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or for improper double patenting.

16. At least claims 15, 16, 18-20, and 23 of the '149 patent are rendered obvious, under 35 U.S.C. § 103(a) based on, *inter alia*, the disclosures of "A Treatise on Beverages on The Complete Practical Bottler: Full Instructions For Laboratory Work with Original Practical Recipes For All Kinds of Carbonated Drinks Mineral Waters Flavorings Extracts Syrups Etc." 559 (New York Dick & Fitzgerald Publishers, 1888); "A Practical Treatise on Materia Medica and Therapeutics," 470-73 (New York D. Appleton and Company 3rd ed. 1879); the contents of the FDA report entitled "Science Backgrounder: Safety of Sodium Phosphates Oral Solution," released on September 17, 2001; and/or, Davis, G.R., *et al.*, *Development of a Lavage Solution Associated with Minimal Water and Electrolyte Absorption or Secretion*, Gastroenterology 78: 991-5, 1980.

17. Cypress is entitled to a declaration that the claims of the '149 patent are invalid.

18. This is an exceptional case under 35 U.S.C. § 285 entitling Cypress to an award of attorneys' fees in connection with this action.

REQUEST FOR RELIEF

WHEREFORE, Cypress prays that this Court enter judgment:

a. dismissing the Complaint with prejudice, and denying each and every prayer for relief contained therein;

b. that no valid claim of the '149 patent has been, or is being, infringed by Cypress;

c. that the claims of the '149 patent are invalid;

d. that this case is exceptional within the meaning of 35 U.S.C. § 285;

e. ordering that all costs and expenses of this action, including reasonable attorneys' fees, be awarded to Cypress; and,

f. awarding to Cypress such further relief as this Court may deem necessary, just, and/or proper.

Dated: January 4, 2013

/s/ Steven Lieberman

Steven Lieberman
Glenn E. Karta
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14th Street, N.W., Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040
Facsimile: (202) 783-6031
slieberman@rfem.com
gkarta@rfem.com

Attorneys for Defendant
Cypress Pharmaceutical, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 4, 2013, a true and correct copy of the foregoing **ANSWER AND COUNTERCLAIMS OF DEFENDANT CYPRESS PHARMACEUTICAL, INC.** was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Erik van Leeuwen
Erik van Leeuwen
Litigation Operations Manager
Rothwell, Figg, Ernst & Manbeck, P.C.